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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/067,638	04/28/98	COVISERT	L ISIS-2960

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EXAMINER

MARSCHEL, A

ART UNIT	PAPER NUMBER
1631	6

DATE MAILED:

11/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/067,638	Applicant(s) Cowser et al.
Examiner Ardin Marschel	Group Art Unit 1631

Responsive to communication(s) filed on Aug 15, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1835 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- Claim(s) 47, 48, 50, and 52-67 is/are pending in the application.
~~Claims~~, Claim(s) 1-46, 49, and 51 have been canceled. ~~Claims withdrawn and considered~~ is/are allowed.
 Claim(s) _____ is/are rejected.
 Claim(s) 47, 48, 50, and 52-67 is/are objected to.
 Claim(s) _____ is/are subject to restriction or election requirement.
 Claims _____

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' arguments; filed 8/15/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 47, 48, 50, and 52-67 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is reiterated and maintained from the previous office action, mailed 5/9/00, and as necessitated by amendment regarding newly submitted claims. Applicants argue that written basis is provided for the claimed systems by pointing to specific descriptions in the specification. Consideration of these descriptions revealed that none of these descriptions describe the claimed system. Generic systems are suggested in the page 8, line 2, description but this generic suggestion fails to specify the "three" device system of instant claim 47, for example. The argued Dictionary definition also lacks such a three device system definition. Then specific descriptions of lists of optional methods or devices are cited at

pages 14-19, Table 1, 61-62, Figures 18 and 19, 39-52, and Figures 23 and 24; each responded to as follows: Pages 14-19 starts with the phrase "Assembly of Target Nucleotide Sequence" and proceeds to describe the assembly of a target sequence from sequenced fragments. This is not what the first device of claim 47 is directed to. The first device of claim 47 prepares a virtual oligonucleotide library from a target and not the other way around as noted in the above phrase from page 14. It is not understood what applicants intend by citing a section which performs the opposite of what is claimed for written support. On page 15, line 24, this section then discusses polypeptide forming nucleic acid, or cDNA, as to assembly as well as targeting oligonucleotides. It is noted that claim 14 is not directed to this practice regarding any polypeptide or cDNA practice. Although applicants indicated pages 14-19 regarding this issue, finally starting at section 3 on page 18 is there virtual oligonucleotide generation described. This section 3 also requires that chemistries that enhance duplex formation be evaluated, in step 304 all possible oligonucleotides of a desired length capable of hybridizing to the target are generated, and lastly in step 305 oligonucleotide chemistry is evaluated; none of which are limitations in claim 47. Thus, it is not understood how pages 14-19 give written basis for the first device in claim 47. Table 1 is then cited which only lists data sources for

target sequences which lacks any description of library preparation as in the first device of claim 47. Pages 61-62 is then pointed to which, upon consideration, describes a database handling system involving storing chemical structure, evaluating RNA folding etc., raw instrument output storage, and staff communication and scheduling; none of which are in claim 47 as limitations. Figures 18 and 19 are then pointed to which detail flow charts with detailed operations cited thereon, again none of which are limitations of claim 47. Then pages 39-52 and Figures 23 and 24 are cited for support. Consideration of pages 39-52 and Figures 23 and 24 reveals details of oligonucleotide synthesis which has been acknowledged in the previous office action as being disclosed, but nowhere in these disclosures is there a system as given in claim 47, and now newly added claim 59. Thus, even the selection of unrelated device descriptions from the instant specification will fail to result in the system practices of claims 47 or 59 thus supporting this rejection.

Applicants then point to pages 55-58 for support regarding the fourth device of claim 58. Consideration of these pages failed to reveal any fourth device description. An assay directed to antisense effects with a numerous details are described on said pages but nowhere is there description of adding this device to three other devices as would be required for the practice of claim 58 nor that the device is a generic device for assaying a

generic "biological" property as required in claim 58. Thus, the NEW MATTER rejection is still deemed proper regarding claim 58. Applicants have amended claim 48 to remove its specific NEW MATTER issue. Claim 52 is then argue that Example 14 gives written basis for eliminating members of a library based on a set of criteria. Consideration of Example 14 reveals that this Example is directed to target position, of oligos to be synthesized, or site selection as given on page 103, lines 16-21. Then on page 104, lines 14-17, a threshold value is selected below or above which all sites will be eliminated. These are the closest Example 14 descriptions to claim 52. This Example 14 description is not the generic member elimination of claim 52 but rather the elimination of "sites" which are firstly not library members but target sites. Also, claim 52 lacks a threshold determination for use of site elimination above and below said threshold value. Thus, the Example 14 argued by applicants fails to support the generic claim 52 limitations. Applicants then argue that claim 53 is supported in the specification at page 25, line 35, through page 26, line 22; and claims 54 and 55 are supported by pages 26-39. Consideration of these pages has overcome this NEW MATTER rejection regarding the specific limitations of claims 53-55 per se, but it is still noted that claims 53-55 are included as rejected under the NEW MATTER rejection of claim 47 due to their dependence from claim 47.

The disclosure is objected to because of the following informalities:

In the specification on page 57, line 22, the citation of a website is present. Such hyperlink citation must be deleted due to being improper. See MPEP 608.01(p), section I.

Appropriate correction is required.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers for this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M.

to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 3, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER